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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,027	12/22/2006	Karim Ioualalen	127137.0101	7316

27557 7590 10/15/2008

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EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,027	IOUALALEN ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *23 Sept 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their timely reply filed on 8 April 2008, in the matter of 10/550,027.

Applicants' election **with traverse** of Group I, claims 1-14 in the reply filed on 8 April 2008 is acknowledged. Applicants traverse the lack of unity on the grounds that "the claims contain a common technical feature that defines over [Blichare] (USPN 4,132,753".

The Examiner respectfully finds Applicants' traversal unpersuasive, as is evident from the rejections under §102 and §103 set forth below, and maintains that no special technical feature has been presented which overcomes the invention practiced by Blichare et al.

Since the instant application is the national stage entry for PCT/FR04/00729, restriction of the claims is deemed proper where a lack of unity can be demonstrated among the presented claims (see MPEP §1850 and PCT Rules 13.1 and 13.2). In the instant case, the Examiner further maintains that Groups I-III do not correspond to a single general inventive concept and lack the same special technical feature as evidenced by the reasons already made of record, most notably the invention practiced by Blichare et al.

In view of the forgoing, the requirements are deemed proper and are therefore made **FINAL**.

Claims 15-20 are acknowledged are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction requirement between the compositions and method.

The remaining claims 1-14 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statement (IDS), filed 23 September 2005 is acknowledged and has been reviewed.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Objections

Claims 4-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative and/or cannot depend from any other multiple claim(s). See MPEP § 608.01(n). Accordingly, the claims 4-14 have not been further treated on the merits.

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In view of Applicants' special definition for the term "galenic system" as set forth in the instant specification (see p. 7, lines 9-12), the Examiner considers the limitation wherein the particles are in "spherical form" to be an inherent

property of a particle or "droplet", particularly since it is unclear as to what other shape a droplet would take.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation wherein the particles are solid at a temperature of

"up to 45°C", and the claim also recites that the particles are solid at a temperature of "up to 37.5°C" which is the narrower statement of the range/limitation.

Herein, and for the purposes of examination on the merits, the temperature limitation, as recited in claim 2, absent some material difference in the properties of the claimed composition, is considered by the Examiner to be directed toward the instantly claimed composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Blichare et al. (USPN 4,132,753).

The instant claims are directed to a system comprising spherical, hydrophobic particles wherein said particles comprise at least one hydrophobic wax, and at least one non-neutralized fatty acid. With regard to the limitation, wherein the system is solid at a temperature of up to 45°C, as recited in claim 2, until some material difference in the properties of the claimed composition are demonstrated distinguishing it from the art, said limitation is considered by the Examiner to be directed toward the instantly claimed composition.

Blichare et al. teach production of spherical, controlled-release granules comprising the active and a finely-divided wax-like material (claims 1 and 13). Said wax-like material is taught as consisting of waxes such as white beeswax, castor wax and Carnuba wax (claim 2). The wax-like material is also taught as comprising non-neutralized fatty acids such as myristic and stearic acids (claim 2).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lantz et al. (USPN 3,146,167).

Lantz et al. teach an oral pharmaceutical preparation having sustained release properties comprising solid substantially spherical lipid pellets having a solid medicament (claim 3). The sustained release or "time-delay" release material is taught as comprising admixed waxes such as Carnuba wax, beeswax and mineral wax, and fatty acids, such as stearic, lauric or myristic acids (col. 3, lines 41-51 and lines 58-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blichare et al. (USPN 4,132,753) in combination with Lantz et al. (USPN 3,146,167).

The instant claims are directed to a system comprising spherical, hydrophobic particles, as discussed above.

The teachings to Blichare et al. are discussed above. Blichare further teaches in claim 1, that the melting point of the wax-like material is between about 30°C and about 100°C. Melting point temperature ranges for some of the wax-like material components are also taught (col. 3, lines 12-26).

The teachings to Lantz are also discussed above. Lantz further advantageously teaches that the time-release or sustained release material will be solid at room temperature, but also has a low melting point of from 40°C to about 150°C (col. 3, lines 36-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a system of galenic (e.g. lipidic droplet) particles comprising at least one hydrophobic wax and at least one non-neutralized fatty acid, modify the proportions of the ingredients to attain the desired melting point temperature, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the inventions practiced by both Blichare et al. and Lantz et al. overlap in their teachings of solid,

spherical-shaped, active-infused, pellet compositions whose release material is comprised of wax materials (e.g. Carnuba, bee and vegetable waxes) as well as overlapping fatty acids (e.g. stearic and myristic acids). Given the overlap in hydrophobic release materials, it then follows, absent any unexpected results that the materials also overlap in their respective melting points.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615